IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.,*

Plaintiffs,

CV-12-0763 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

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PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND SUMMARY JUDGMENT

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The FDA's actions in this case are a textbook example of arbitrary and capricious conduct by an agency which, instead of protecting the public health as it should, has succumbed to political pressure and put politics above women's health at every turn. Plaintiffs have set forth sufficient facts to demonstrate that a preliminary injunction should issue because they have shown a likelihood of success on the merits of their claim that the FDA's actions upon remand were arbitrary and capricious, that irreparable harm has occurred and will continue to occur without injunctive relief, and that the public interest supports a preliminary injunction. Similarly, no genuine issues of material fact exist and Plaintiffs are therefore entitled to summary judgment as well. Indeed, the few documents Defendants have filed with this Court since Plaintiffs filed their underlying motion have served to confirm the arbitrary, capricious and bad faith behavior in which Defendants engaged upon remand.

I. PRELIMINARY STATEMENT

Plaintiffs set forth the facts most relevant to this Court's decision on Plaintiffs' Motion for Preliminary Injunction and Summary Judgment (ECF2 No. 2),[1] demonstrating the depth and breadth of the FDA's arbitrary and capricious conduct over the many years it has dragged out this case, including its shameless continuation of such conduct after remand.

In 2001, Plaintiff Association of Reproductive Health Professionals ("ARHP") and other organizations filed a Citizen Petition asking the FDA to switch Plan B and all similar levonorgestrel-based emergency contraceptives ("EC") from prescription-only to over-the-counter ("OTC") status. During the same period, the manufacturer of Plan B submitted a series of supplemental new drug applications ("sNDAs") in an attempt to switch that drug to OTC status. For over a decade, there has been overwhelming evidence that EC meets the standards for

[1] In this brief docket numbers designated by "ECF" are the docket numbers for Case No. 05-cv-0366, and those designated "ECF2" are for 12-cv-763, the case number for the reopened case.

OTC access for all women.[2] *See Tummino v. Torti*, 603 F. Supp. 2d 519, 528 (E.D.N.Y 2009) (discussing FDA scientists' recommendations that EC be made OTC for women of all ages); Mem. in Supp. of Pls.' Mot. for Prelim. Inj. & Summ. Judgm. ("Pls.' Mot. for PI/SJ") at 8-9 (ECF2 No. 2). It is undeniable that when the second Plan B sNDA was reviewed in 2004, there was "nearly uniform agreement among FDA scientific review staff that women of all ages could use Plan B without a prescription safely and effectively." *Tummino*, 603 F. Supp. 2d at 523.[3] Dr. Rosebraugh, Deputy Director of the Division of OTC Drugs, noted that "[Plan B] ha[d] more information available to allow us to predict consumer behaviors than any drug the Division has approved for switch in recent memory." In addition, FDA Advisory Committee members (1) voted unanimously that Plan B was safe for OTC use; (2) voted 27-1 that the actual use study submitted with the last Plan B sNDA was generalizable to the overall population; and (3) recommended that Plan B be made available OTC without age or other restrictions. *See* Tummino 10530, 10758, 10762, 10749, 10754, 10783, 10784, 10792 (contained in ECF No. 248-3).[4] In general, the FDA follows Advisory Committee recommendations for OTC switches. *Tummino*, 603 F. Supp. 2d at 528 ("the FDA has followed advisory committee recommendations in every OTC switch application in the last decade"). If the agency lacks confidence in the applicability of manufacturers' studies to younger consumers, it issues label warnings for products. Pls.' Mot. for PI/SJ at 35 (ECF2 No. 2).

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[2] As Defendants concede, by statute, the default status for drugs is OTC. *See* Defs.' Resp. to Pls.' R. 56.1 Statement of Material Facts Not in Dispute (ECF2 No. 38); Pls.' Fifth Amend. Compl. Ex. U (ECF No. 207 at 32). A drug is suitable for OTC use when it is found to be safe and effective for self-administration and when its labeling clearly provides directions for safe use and warnings regarding unsafe use, side effects, and adverse reactions. *See* 21 C.F.R. § 310.200(b); § 330.10(a)(4); *Tummino v. Torti*, 603 F. Supp. 2d 519, 525 (E.D.N.Y. 2009). A drug shall be limited to prescription status only when it is not safe for use except under the supervision of a licensed practitioner because of its toxicity or other potentiality for harmful effect. 21 U.S.C. § 353(b)(1)(A).

[3] The manufacturer of Plan B's corporate successor, Teva Women's Health, Inc. ("Teva"), currently markets Plan B One Step, a one-pill EC product. Since the evidence shows that the two-pill product is safe and appropriate for OTC access without point-of-sale restrictions for all women, the one-pill product meets those standards as well, since it contains exactly the same ingredients and total dosage.

[4] Documents from the record in this case will be referred to by their stamped identification of "Tummino PAGE" where "PAGE" is the number stamped on the document.

But for EC the scientific recommendations were not the last word. Even as the FDA was reviewing the Plan B sNDAs and the Citizen Petition, White House staff began to believe that allowing full OTC access to EC would be a political liability, and this belief was communicated to decision-makers at the FDA. *Tummino*, 603 F. Supp. 2d at 528-29. Thus, over the past decade various members of the FDA (most recently Secretary Sebelius) have intermittently advanced the post-hoc, internally inconsistent, and logic-defying position that the data supporting the various OTC switch requests is insufficient to allow such access for teens.

This position is implausible, for several reasons. First, the actual use and label comprehension studies submitted with the Plan B sNDA seeking an OTC switch included data on teens, *Tummino*, 603 F. Supp. 2d at 528, 530-31, which the studies submitted in support of many other *granted* OTC switch applications for other drugs do not. *See id.* at 531. Second, prior to filing the sNDA, the Plan B manufacturer was assured by "FDA staff . . . that the actual use study, the study the FDA considered 'pivotal' to the application, 'appeared to be adequate for filing.'" *Id.* at 526. The FDA specifically informed the Plan B sponsor that results from trials in the adult population could be extrapolated to the post-menarchal pediatric population, as is common FDA procedure. *Id.*at 526-27. In addition, FDA review staff concluded that "the body of evidence available" to the FDA regarding adolescents and Plan B was "tremendously augmented" by other behavioral studies about EC that FDA reviewers considered when concluding that Plan B met the standards for OTC access. Tummino 30868 (ECF2 No. 31-1); *see also Tummino*, 603 F. Supp. 2d at 528, 530-31, 533. *See also* Pls.' Corrected Resp. to Defs.' Resp. to Order to Show Cause ("Pls.' Resp. to OSC") at 6-15 (ECF2 No. 36). As Dr. Rosebraugh stated, "it is unclear what additional data could be provided on adolescent use that would be sufficient to lift the age restriction in the future." Tummino 31027 (ECF2 No. 31-1 at 126).

Little did Dr. Rosebraugh know that that his statement would foreshadow and epitomize the events that have unfolded over the following eight years.

Despite the scientific evidence, Dr. Steven Galson, Acting Director for the Center for Drug Evaluation and Research (CDER), fearing for his job, bowed to political pressure to block EC from OTC access. *Tummino*, 603 F. Supp. 2d at 529 (noting that White House pressure was transmitted down to Dr. Galson). Central to Dr. Galson's "decision" that the data for adolescents was insufficient to permit OTC availability was his conclusion that "it was invalid to extrapolate data from older to younger adolescents in this case" because of the difference in cognitive development between early- and mid-adolescence. Dr. Galson himself acknowledged that this rationale was novel and unprecedented for an OTC application, and this Court found that it stemmed from political rather than health and safety concerns. *Tummino*, 603 F. Supp. 2d at 528; Pls.' Mot. for PI/SJ at 12 (ECF2 No. 2). Indeed, this Court noted that Dr. Galson reached his conclusion without becoming fully familiar with the contents of the record, which in fact, as noted above, *did* contain additional studies containing data for adolescents, including eight behavioral studies. *Tummino*, 603 F. Supp. 2d at 530. And while the scientific review staff found the additional studies very relevant to and supportive of an OTC switch, Dr. Galson determined that they were not, for reasons that this Court found to lack credibility. *See id.* at 533.[5] In the end, the FDA abandoned its own precedents and approved Plan B for OTC status only for persons 18 and older, implemented the behind-the-counter ("BTC") regime, and denied the Citizen Petition. *Id.* at 536-38.

Plaintiffs challenged the FDA's treatment of the Plan B sNDAs, the denial of the Citizen Petition, and the establishment of the dual prescription regime for EC. *See* Pls.' Fifth Am.

[5] Counsel for Defendants re-argued these very same, previously rejected, concerns at oral argument on April 27, 2012. April 27, 2012 Hr'g Tr. at 59-62.

Compl. ¶ 1 (ECF No. 207). In 2009 this Court held that the FDA's actions, described above, were arbitrary and capricious and taken in bad faith. *Tummino,* 603 F. Supp. 2d at 544-49. More specifically, this Court found that the FDA's decisions on Plan B took political considerations into account, had implausible justifications, and departed in significant ways from the agency's normal procedures for OTC requests. *Id.* at 523-24**.** As a result, it vacated the denial of the Citizen Petition and remanded it to the FDA "for reconsideration of whether to approve Plan B for over-the-counter status without age or point-of-sale restrictions." *Id.* at 524.

As detailed in Plaintiffs' previous filings, the FDA ignored this Court's Order to reconsider the Citizen Petition, Pls.' Mot. for PI/SJ at 13-18 (ECF2 No. 2), and even argued that the Order did not require it to reconsider the petition *at all*, Def.'s Mem. in Opp'n to Contempt 14-17 (ECF No. 315). Just as egregiously, the FDA also completely disregarded this Court's findings and reasoning. Instead of reviewing the Citizen Petition/Plan B files in accordance with agency norms, including extrapolating data to younger teens, or explaining why such norms should be abandoned for this drug but not others, the FDA dug in its heels, parroting Dr. Galson's politically-tainted conclusions that additional teen-specific data was necessary for a full OTC switch. In fact, within two months of receiving this Court's order, the FDA informed the Plan B manufacturer that "[t]o support a full OTC switch of Plan B without age restriction, you will need to fully address the concerns regarding nonprescription use of Plan B by women 16 years of age and younger that were articulated in Dr. Steven Galson's memorandum dated August 26, 2005 and our May 6, 2004 letter." Defs.' Mem. of Law in Opp. to Pls.' Post-Remand Mot. for Prelim. Inj. & Summ. Judgm., Ex. F at 2 ("Defs.' Opp. to Pls.' Mot. for PI/SJ") (ECF2

No. 37-1).[6]

Notably, in this letter, the FDA originally told the manufacturer that it could satisfy the concerns about adolescent women by using *currently available* data—no mention was made of a need for new studies. *Id.* But at some point the FDA changed course, and concluded that Teva *must* conduct new adolescent-specific studies. *See, e.g.,* Hr'g Tr. 15, April 27, 2012 (counsel for Teva stating that his client was told it would have to produce research justifying OTC access for adolescents). The FDA demanded new studies even though it already had obtained the 2009 Cremer label comprehension study (the type of large, adolescent-specific study it had claimed would be needed to grant the Citizen Petition) which confirmed that adolescents have "comprehension equal to adults of the key points necessary for safe and effective EC use." Cremer Decl. ¶ 3 (ECF2 No. 29); *see also* Raymond Decl. 2 ¶ ¶ 35-38 (ECF2 No. 28).

In order to satisfy the FDA's "concerns" and demands, Teva agreed to conduct new studies designed to provide such data for its newer one-pill EC product (Plan B One-Step). Teva ultimately decided to file an sNDA seeking an unrestricted OTC switch for all ages for that product and not Plan B, the original two-pill product. *See* Defs.' Opp. to Pls.' Mot. for PI/SJ, Ex. F (ECF2 No. 37-1). If Teva submitted new studies and the FDA granted the Plan B One-Step sNDA on the basis of those studies, the FDA would have the option of deeming Teva's data "essential" to granting the sNDA. Such a determination would give Teva three years of exclusivity. 21 U.S.C. § 355. Indeed, the FDA has admitted that it planned to grant such exclusivity. Letter from Janet Woodcock, Dir., CDER at 6 (Dec. 12, 2011) ("Cit. Pet. Denial Ltr.") (ECF No. 341-1). Such a determination would have, by definition, denied Plaintiffs and

[6] Since then, the FDA has repeatedly defended both its years-long refusal to reconsider the Citizen Petition and its denial of the Citizen Petition as a result of Plaintiffs' "failure" to submit such unnecessary data. *See* Letter from Janet Woodcock, Dir., CDER, at 5-6 (Dec. 12, 2011) (ECF No. 341-1) (hereinafter "Cit. Pet. Denial Ltr."); Def.'s Mem. in Opp'n to Contempt at 8, 24-25, 31 (ECF No. 315); Def.'s Reply to Pls.' Resp. To Apr. 29, 2011 Order & Questions at 4 (ECF No. 333) (expressing doubt that Citizen Petition would be granted without new evidence); *id.* at 6 (stating that two-pill generics could seek all ages OTC status "were they to obtain appropriate data"); Pls.' Mot. for PI/SJ at 15-18 (ECF2 No. 2).

the public full OTC access to the generic products, which should have been available for years now. Pls.' Ltr. Resp. to Court Order (ECF No. 329). Access to generic forms of EC is crucial. Plan B One-Step generally costs 10-20% more than the generic.[7] Moreover, in 2010 Plan B One-Step accounted for 35 percent of EC sales, and the generic Next Choice accounted for 65 percent. Ctr. for Drug Evaluation & Research, Office of Surveillance & Epidemiology, Drug Use Review: Single-Ingredient Levonorgestrel Oral Tablets (Dec. 6, 2011).[8]

Meanwhile, while all these negotiations with the manufacturer were taking place over several years, the FDA made no effort to revisit the Citizen Petition, despite having essentially publicly announced its position that the Citizen Petition, without additional data, was insufficient to support an OTC switch for women of all ages.

The FDA ultimately determined that Plan B One-Step was suitable for full OTC access, FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (Dec. 7, 2011) (ECF No. 339-2). But in yet another example of political interference with scientific decision-making on EC, Secretary Sebelius, after consultation between her staff and White House staff, Defs.' Answer to First Am. Supplemental Compl. ¶ 38 (ECF2 No. 53), ordered the FDA to deny Teva's sNDA. Secretary Sebelius stated the sNDA should be denied for almost the same reasons that Dr. Galson had provided many years ago, Pls.' Mot. for PI/SJ at 17 (ECF2 No. 2), even though this Court had already found those reasons to be improper, *Tummino*, 603 F. Supp. 2d at 523. Despite this consistent reliance on the red herring of cognitive development, neither Dr. Galson nor Secretary Sebelius has credibly explained why cognitive differences between older and younger adolescents would make it appropriate to extrapolate data for almost

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[7] *See* National Women's Law Center, *Accessing Non-Prescription Emergency Contraception: The Basics*, http://www.nwlc.org/sites/default/files/pdfs/ec_otc_basics_4.18.12.pdf.

[8] *Available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM288778.pdf (last visited May 21, 2012).

all other drugs, but not EC. Nor has the FDA (excluding Secretary Sebelius) explained why extrapolation from older to younger teens is inappropriate for studies of the EC two-pill products, but appropriate for the one-pill product, a necessary corollary of the agency's position on the adequacy of the data supporting the sNDAs for Plan B versus Plan B One-Step.

Even if Secretary Sebelius had not intervened, an FDA determination that the new studies Teva submitted were "essential" to approving Plan B One-Step for full OTC access would have been mere political cover, not a plausible scientific determination. First, the information from the actual use and label comprehension studies Teva conducted for the Plan B One-Step sNDA, all of which are in the public domain, as well as the results of Dr. Cremer's large adolescent-specific label comprehension study of the two-pill product, published in 2009, merely *confirmed* the results shown by the prior studies the FDA considered for the two-pill OTC switch almost a decade ago. Raymond Decl. 1 ¶¶ 34-35 (ECF No. 349); Raymond Decl. 2 ¶¶ 13-14, 41-42 (ECF2 No. 28); Harper Decl. ¶¶ 19-20 (ECF No. 347); Pls.' Resp. to OSC at 7-11 (ECF2 No. 36) (discussing, that, among other studies, Dr. Cremer's study showed high comprehension among adolescents of five key concepts tested for using EC). Second, the agency still has yet to provide a credible explanation for why it would be inappropriate to extrapolate data from the earlier studies for this particular drug. Finally, the FDA's conclusion that those studies were "essential" is all the more disingenuous since the agency had informed Teva in 2009, after this Court's remand, that it could address the agency's "concerns" about adolescents using data that already existed at that time. Defs.' Opp. to Pls.' Mot. for PI/SJ, Ex. F at 2 (ECF2 No. 37-1).

Six days after Secretary Sebelius issued her directive, the FDA finally denied the Citizen Petition. In addition to all of the bad faith conduct leading up to that point discussed above, the denial itself was arbitrary and capricious. The FDA reasoned that there was insufficient data to

support the petition because: (1) there were no actual use and label comprehension studies submitted with the Citizen Petition (even though the Court ruled that the studies submitted with the Plan B sNDAs were applicable, *Tummino*, 603 F. Supp. 2d at 543); (2) Dr. Galson had previously determined that adolescent-specific studies were necessary; (3) Plaintiffs failed to submit additional data after the FDA re-opened the docket for the Citizen Petition; (4) having recently determined that the data submitted with Teva's sNDA was "essential," *a fortiori*, if such essential data was missing from the two-pill product studies, the two-pill products could not be approved for OTC access, April 27, 2012 Hr'g Tr. at 125:1-13, 20-25; 128:15-129:7; and (5) the essential data from the one-pill studies were inapplicable to the two-pill products because of their "more complicated directions for use." Pls.' Mot. for PI/SJ at 17-18 (ECF2 No. 2).

The FDA's reasoning that the Plan B One-Step studies were essential but could not be generalized to the two-pill products is particularly brazen given that documents recently filed by Defendants demonstrate that the FDA had previously informed Teva that many aspects of the data generated from those trials *would* be applicable to the two-pill product. Letter from Andrea Leonard-Segal to Duramed Pharmaceuticals, Inc. [9] at 2 (Dec. 17, 2010) (ECF2 No. 23-3). Indeed, the FDA provided Teva with specific examples of the data from the One-Pill studies that could be applicable to the two-pill products, which encompassed *5 of the 6 elements that the FDA determined were "key elements" of those studies.*[10] In fact, the medical research and the very existence of Plan B One-Step show that the timing of the second pill for a two-pill EC Product is not crucial to the product's safety or efficacy; the existing research shows that young teens can

[9] Duramed was the original manufacturer of Plan B, the corporate predecessor to Teva Women's Health, Inc.

[10] The letter discussed the following overlapping elements: the product is indicated for prevention of pregnancy after unprotected sex; taking the product as soon as possible but within 72 hours; that the product should not be used as regular birth control; that the product will not protect against sexually transmitted diseases, and that the safety data overlaps. Letter from Andre Leonard-Segal to Duramed Pharmaceuticals, Inc. at 2 (Dec. 17, 2010) (ECF2 No. 23-3). The denial of the Citizen Petition listed those 5 elements, along with the fact that Plan B One-Step should not be used by women who are already pregnant, as the "key elements" tested by Teva's label comprehension study. Cit. Pet. Denial Ltr. at 8-9 (ECF No. 341-1).

and do follow those directions, Pls.' Resp. to OSC at 10-11 (ECF2 No. 36);[11] and many currently OTC products have much more complicated instructions. *See* Raymond Decl. 1 ¶¶ 10, 36 (ECF No. 349); Pendergast Decl. ¶ 21 (ECF No. 348); April 27, 2012 Hr'g Tr. at 54-55, 79:4-13, 87:21-22, 94:1-19. Even if the FDA's concerns about following the two-pill products' directions were legitimate, there is no reason for the drug to remain prescription only because the unrebutted evidence shows that interaction with a clinician has no effect on when and how women take EC. Raymond Decl. 2 ¶¶ 3, 6-9, 11-15, 18, 25 (ECF2 No. 28). In sum, the evidence has been clear from the beginning that EC is safe and effective for OTC use, and the FDA's actions over the past decade have been about avoidance and obfuscation, not about science or medicine. The FDA's reasoning for denying the Citizen Petition on remand thus strains all credulity.

Given the foregoing facts, Plaintiffs have, at the very least, demonstrated a likelihood of success on the merits of their claim that the FDA's actions on remand were arbitrary and capricious. Because the other standards for a preliminary injunction are also satisfied, this Court should immediately enter a preliminary injunction directing the FDA to allow levonorgestrel-based EC to be made available OTC to all women without point-of-sale restrictions. In addition, because there are no genuine issues of material fact present, this Court should also grant Plaintiffs summary judgment.

[11] Indeed, the actual use study submitted with the Plan B sNDA seeking OTC status showed that the group that had the *highest* percentage of compliance with following the instructions to take the second pill 12 hours after the first was the 16 year old and under group. Pls.' Resp. to OSC at 6, 10, 12-15 (ECF2 No. 36). Defendants have failed to rebut this evidence.

II. PLAINTIFFS ARE ENTITLED TO A PRELIMINARY INJUNCTION DIRECTING THE FDA TO IMMEDIATELY ENABLE EC TO BE MADE AVAILABLE TO WOMEN OF ALL AGES OVER-THE-COUNTER AND WITHOUT POINT-OF-SALE RESTRICTIONS.

A preliminary injunction is warranted when a party seeking a mandatory injunction demonstrates (1) a clear or substantial likelihood of success on the merits; (2) irreparable harm absent injunctive relief; and (3) that the public's interest weighs in favor of granting an injunction. *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011); *Doninger v. Niehoff*, 527 F.3d 41, 47 (2d Cir. 2008).[12]

A. Plaintiffs Have Shown A Likelihood of Success on the Merits of Their Claim that the FDA's Actions Upon Remand Were Arbitrary and Capricious.

1. The FDA's Actions Upon Remand Were Arbitrary and Capricious.

When determining whether an agency decision was arbitrary or capricious, the reviewing court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation and citation omitted). As part of this test, the reviewing court must also consider whether the agency has adhered to its normal practice or has provided a sufficient explanation for its departure from such normal practices. *See INS v. Yang*, 519 U.S. 26, 32 (1996) (holding that an irrational departure from general agency policy could constitute arbitrary and capricious action); *Atchison, Topeka, & Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973) (plurality opinion) (an agency has a "duty to explain its departure from prior norms").

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[12] Despite Defendants' suggestion, there is no difference between the standard for a preliminary injunction set forth by either of the parties. *Compare* Pls.' Mot. for PI/SJ at 19 (ECF2 No. 2) with Defs.' Opp. to Pls.' Mot. for PI/SJ at 6 (ECF2 No. 37). Both parties recognize that a "substantial likelihood of success" is required in this case. *Id.* Defendants are, however, wrong that the "clear showing" language used in some cases requires something more than a "substantial likelihood" of success on the merits. The very case Defendants cite for this proposition plainly states that "the variation in language does not reflect a variation in meaning." *Tom Doherty Assocs. v. Saban Entm't, Inc.*, 60 F.3d 27, 34 (2d Cir. 1995).

The FDA's actions since this Court's 2009 remand are a stunning exemplar of arbitrary and capricious agency conduct. Despite this Court's finding that Dr. Galson's "concern" about adolescent usage was politically tainted and made in bad faith, the FDA, after remand, informed the manufacturer of Plan B that it would nonetheless need to address these specious concerns. While the FDA initially stated that existing literature would suffice, it later switched tacks and demanded new studies. Meanwhile it ignored this Court's order that it reconsider the Citizen Petition. When it finally got the unnecessary new studies it had demanded, it denied the sNDA anyway because of the lack of data on younger adolescents who use EC in such small numbers that it would be impossible to achieve a reliable sample size. Then, almost three years after remand, it denied the Citizen Petition as well, even though such a denial was inevitable once the FDA decided to require new studies.

The FDA originally rejected the OTC switch applications "despite nearly uniform agreement among FDA scientific review staff that women of all ages could use Plan B without a prescription safely and effectively." *Tummino,* 603 F. Supp. 2d at 523. As this Court found, the FDA's decisions on EC the first time around took political considerations into account, provided implausible justifications, and departed from normal agency procedures. *Id.* On remand, the FDA ignored this Court's previous findings, continued to depart from normal agency procedures, relied on politically tainted reasoning, and provided implausible justifications for refusing to grant OTC access for EC. In sum, it is difficult to imagine a more arbitrary and capricious sequence of events and decisions. As this Part demonstrates, none of Defendants' arguments to the contrary have any merit.

2. The FDA Post-Remand Actions Are Not Entitled to Deference.

The FDA claims that its actions on remand "are essentially non-reviewable," Defs.' Opp. to Pls.' Mot. for PI/SJ at 28 (ECF2 No. 37), and that agency determinations based on the evaluation of scientific information require particularly deferential treatment from the reviewing court, *id.* at 29-30. Defendants are wrong. Indeed, even they admit that an agency cannot demand deference for its scientific "expertise" when, as in this case, this Court has specifically found that the agency's actions are arbitrary and capricious and based on political pressure. *See Tummino*, 603 F. Supp. 2d at 544-47; April 27, 2012 Hr'g Tr. at 51, 64-66; Defs.' Opp. to Pls.' Mot. For PI/SJ at 29-31.

Moreover, while it is true that an initial review of agency action usually requires deference to the agency, *Tummino*, 603 F. Supp. 2d at 542, when reviewing agency action *after remand*, courts apply a much greater degree of scrutiny. *Greyhound Corp. v. Interstate Comm. Comm'n*, 668 F.2d 1354, 1360 (D.C. Cir. 1981). In particular, after a court has remanded with explicit instructions to the agency, the court must examine the agency's actions with care to ensure that the earlier decision has been followed. *Guillen-Garcia v. INS*, 60 F.3d 340, 344 (7th Cir. 1995). This is especially necessary where, as here, the agency "arrives at substantially the same conclusion as an order previously remanded by the same court." *Greyhound Corp.*, 668 F.2d at 1358. Heeding the warning expounded in *Greyhound Corp.*, this Court must consider the danger that the FDA, "having reached a particular result, may [have] become so committed to that result as to resist engaging in any genuine reconsideration of the issues." *Id.*

Further, this Court is not required—or even at liberty—to simply take the FDA's explanations at face value now that this case has already been remanded once before. The FDA consistently suggests that this Court defer to its "interpretations" of the data, its own regulations,

and any explanations it provides for its actions, no matter how implausible they may seem. Defs.' Opp. to Pls.' Mot. for PI/SJ at 28-31. But when agency action is challenged as arbitrary and capricious, an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicles Mfrs. Assn' v. State Farm Mutual Auto Ins. Co.,* 463 U.S. 29, 42-43 (1983). *See also Catron County Bd. of Comm'rs, N.M. v. U.S. Fish & Wildlife Svc.*, 75 F.3d 1429, 1436 (10th Cir. 1996) (noting that where data conflicted with administrative determination, "[m]erely because the Secretary says it does not make it so"). This is all the more so where, as here, the agency has already had a chance on remand to come to a different determination or credibly explain why it has returned to the same one and they have failed to do so. *See Greyhound Corp.*, 668 F.2d at 1358. In sum, the FDA's complete failure to provide any legitimate explanation for its multiple departures from agency norms and from the conclusions supported by the data cannot be accepted at face value and should be subjected to scrutiny instead.

3. This Court Has the Authority to Consider All of the FDA's Actions on Remand with Respect to the Citizen Petition and Plan B One-Step sNDA.

During the April 27, 2012 hearing, Defendants stated that this Court's consideration of Plaintiffs' claims following remand all boils down to whether the Plan B One-Step studies were "essential." *See* infra Part II(A)(4); April 27, 2012 Hr'g Tr. at 56:13-15. So it is strange that they also argue that the Secretary's and FDA's actions with regard to the Plan B One-Step sNDA are irrelevant to the current matter. Defs.' Opp. to Pls.' Mot. for PI/SJ at 23-28 (ECF2 No. 37). It is also incorrect. While this Court is not reviewing the propriety of the Plan B One-Step sNDA denial *on the merits* as an independent matter, it certainly *can* consider the FDA's actions around

the Plan B One-Step sNDA denial as relevant evidence as to whether the FDA's actions upon remand with regards to the Citizen Petition were arbitrary and capricious. This Court has already recognized that the FDA's decision to consider an sNDA for Plan B in tandem with or instead of a Citizen Petition brings the FDA's actions on that sNDA under review as evidence regarding whether the FDA acted arbitrarily and capriciously. *Tummino*, 603 F. Supp. 2d at 543. This time around, a review of the FDA's actions with regard to the Plan B One-Step sNDA is relevant and necessary given the FDA's reliance on that review to comply with this Court's remand order. *See* Def.'s Mem. in Opp'n to Contempt at 20-21 (ECF No. 315); Pls.' Mot. for PI/SJ at 13-15 (ECF2 No. 2); Cit. Pet. Denial Ltr. at 2 (ECF 341-1).[13] Indeed, as this Court has already noted, it would be impossible to assess the FDA's actions on remand with respect to the Citizen Petition, including its denial, without considering how the agency and Secretary Sebelius handled the Plan B One-Step sNDA. April 27, 2012 Hr'g Tr. at 111:13-15, 18-25.

Finally, even if the FDA had not tied the Citizen Petition directly to the Plan B One-Step sNDA, the FDA has previously made clear that information it reviewed as part of the Plan B One-Step sNDA would be applicable to other EC products because "there are overlapping elements of labeling" between two-pill products and Plan B One-Step, and therefore "some data generated by [the Plan B One-Step] studies may be applicable" to other forms of EC. Letter from Andrea Leonard-Segal to Duramed Pharmaceuticals, Inc. at 2 (Dec. 17, 2010) (ECF2 No. 23-3). Thus the FDA's decision with regard to the Plan B One-Step sNDA is clearly relevant to its ruling on the Citizen Petition.

[13] Despite the FDA's claim to the contrary, the Secretary's decision with respect to the Plan B One-Step sNDA is also relevant to this Court's review of the Citizen Petition. Defs.' Opp. to Pls.' Mot. for PI/SJ at 23 (ECF2 No. 37).. The Secretary acted under her asserted authority as the person "responsible for executing" the Federal Food, Drug, and Cosmetic Act ("FDCA"). Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 3), and, as a result, her actions are the FDA's actions.

4. The FDA's Explanations for Its Arbitrary and Capricious Actions Are Nonsensical and Implausible.

a) The FDA's Demand for New Adolescent Studies and the Significance Attributed to Those Studies Was Arbitrary and Capricious.

If, upon remand, the FDA had reviewed the materials in the record in good faith, it would have come to the same scientifically-supported conclusion reached by non-political decision-makers: i.e., that there was sufficient data to support an OTC switch for EC without any age or point-of-sale restrictions before any new studies were performed. Pls.' Mot. for PI/SJ at 29-41 (ECF2 No. 2); Pls.' Resp. to OSC at 5-15 (ECF2 No. 36). *See Tummino*, 603 F. Supp. 2d at 531. Instead, the FDA told the manufacturer that it would have to address Dr. Galson's "concerns" about adolescent usage, first through the existing literature and then by producing new studies. After an original court finding that the conclusion that the data was insufficient was arbitrary and capricious, the repetition of that finding without review of the data or a new credible explanation is arbitrary and capricious. *See Greyhound Corp.*, 668 F.2d at 1360.

This demand for new studies was particularly arbitrary and capricious because the FDA could and should have extrapolated data about the existing two-pill EC products from older to younger adolescents, as is its usual course, or provided a coherent explanation for why extrapolation was inappropriate. *Tummino*, 603 F. Supp. 2d at 547-549.[14] Defendants argue that a decision by the FDA not to extrapolate is not per se impermissible, Defs.' Opp. to Pls.' Mot.

[14] Despite Plaintiffs' unrebutted evidence that the FDA routinely extrapolates data from older to younger populations when reviewing the safety and effectiveness of contraceptives, and a subsequent Court finding of the same, Defendants continue to argue that extrapolation is not an agency norm. The FDA, however, provides no evidence to support such a contention. To the contrary, its own documents show that "the inability to extrapolate adolescent safety and effectiveness for < 14 year old females is not consistent with how CDER handles approval and distribution of prescription oral contraceptives … In addition, CDER routinely denies sponsors requests to issue[] Written Requests for Pediatric Studies for oral contraceptives as these drugs are considered the same for all menstruating females and additional studies are not necessary." *Id;. see also* 21 U.S.C. § 355c(a)(2)(B)(ii) ("A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group."). Moreover, while it is clear that extrapolation is the norm, 21 U.S.C. § 355c(a) explicitly permits the FDA to waive studies that are impossible or highly impracticable "because, for example, the number of patients is so small" or if the drug product "is not likely to be used in a substantial number of pediatric patients." There is no doubt that such a waiver was made in this case. *Tummino*, 603 F. Supp. 2d. at 532 (citing Tummino 10949)(the "Acting Director of the Division of Pediatric Drug Development … waiv[ed the] pediatric study because of the minimal number of individuals of that age using Plan B").

for PI/SJ at 35 (ECF2 No. 37), and that therefore they were not required to extrapolate from older to younger adolescents for the two-pill EC product after remand. But Plaintiffs do not argue that it is per se impermissible to fail to extrapolate. Rather, they argue that it was arbitrary and capricious not to extrapolate *in the context of this case* because Defendants have failed to credibly explain the departure from agency extrapolation norms with respect to an OTC switch for EC. While Defendants argue that extrapolation would be inappropriate because of the significant cognitive and behavioral differences between adults and younger adolescents, Defs.' Opp. to Pls.' Mot. for PI/SJ at 36 (ECF2 No. 37), these were the exact concerns raised by Dr. Galson, and rejected by this Court as novel, stemming from political pressure, and the result of arbitrary and capricious decision-making. *Tummino*, 603 F. Supp. 2d at 538 (citing GAO Report at 5 (ECF No. 68)); *Tummino*, 603 F. Supp. 2d at 548. (Indeed, the documents upon which Defendants rely to suggest that supposed cognitive differences make extrapolation inappropriate are memorandum drafted by Dr. Galson. *Id.*). But Defendants have failed to explain why such cognitive and behavioral differences are applicable *only with respect to EC products* as opposed to all other products. Thus, the FDA's continued failure to extrapolate without a legitimate explanation is clearly arbitrary and capricious. *See Greyhound Corp.*, 668 F.2d at 1358.

Further, the agency's actions with respect to the Plan B One-Step sNDA merely underscore that no legitimate explanation for the failure to extrapolate is possible. Upon remand the FDA refused to extrapolate from older to younger adolescents to make the two-pill product available OTC without further studies, but when the FDA (before Secretary Sebelius' intervention) was ready to approve the Plan B One-Step sNDA and to make the one-pill EC product available OTC to women of all ages, it was prepared to do so *based on extrapolated data*. FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step

(Dec. 7, 2011) (ECF No. 339-2). This disparate treatment alone is sufficient evidence of arbitrary and capricious agency action. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997); *Doubleday Broadcasting Co. v. FCC,* 655 F.2d 417, 423 (D.C. Cir. 1981)) ("The disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious."). The FDA provides no legitimate explanation for such drastically different treatment, nor could it, considering that these two drugs are biological equivalents.

Given all the surrounding facts, the FDA's determination that the new Plan B One-Step studies were "essential" was also arbitrary and capricious. As discussed *supra* Part I at 10-11, the FDA admitted that five of the six elements tested by the Plan B One-Step studies that it declared "essential" were already reflected in the literature on the two-pill products. So the FDA's only option for supporting its determination that the Plan B One-Step studies were "essential" was to rely on the one difference between the two products: whether they come in one- or two-pill form. But the directions for taking EC in either one-pill or two-pill form are much simpler than those that exist for many OTC products. Raymond Decl. 1 ¶¶ 10, 36 (ECF No. 349); Pendergast Decl. ¶ 21 (ECF No. 348). Thus, the idea that the Teva studies cannot be extended to support access to a two-pill product because they do not demonstrate that adolescents can correctly follow the "two-pill aspect" of the directions for that product is, as this Court noted, "an artificial construct at odds with common sense" that is almost impossible to "make with a straight face." April 27, 2012 Hr'g Tr. at 54-55.[15]

[15] Even putting aside the overwhelming evidence that EC meets the standards for OTC status and the lack of credible arguments to the contrary, on the flip side, Defendants have failed to put forth any rationale whatsoever for the default OTC status to be abandoned for young women under 17. *See* 21 U.S.C. § 353(b)(1)(A) (explaining that a drug shall be prescription status only when it is not safe for use except under the supervision of a licensed practitioner because of its toxicity or other potentiality for harmful effect). The undisputed evidence shows that emergency contraception "does not have any known serious or long-term side effects," *Tummino*, 603 F. Supp. 2d at 522, and that intervention by a health care provider does not impact the timing of the second dose. Tummino 30840-41 (ECF2 No. 31-1 at 84-85). Accordingly, even if timing of the second pill were crucial, Defendants have failed to put forth any reason why EC should be available only by prescription for younger adolescents. *Cf. id.*

b) The FDA's Requirement for Data On Adolescents Who Do Not Use EC In Sufficient Numbers Is Arbitrary and Capricious.

As the record now makes clear, the FDA was unwilling to extrapolate and was insistent that new studies be conducted to provide adolescent data. And yet, once those new studies were provided, the FDA denied the sNDA anyway, on the Kafkaesque grounds that the lack of data about the youngest adolescents, who do not use EC in high enough numbers to provide a reasonable sample size, means EC cannot be made available OTC without restrictions to other adolescents for whom there is more than sufficient data. Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 2).

Taken together, the FDA's statements illustrate the impossibility of ever satisfying its "standards" for data sufficiency to permit EC to become available OTC without restriction. On the one hand, the FDA, and especially Dr. Galson, stress the importance of actual use studies, Defs.' Resp. to OSC at 6-9 (ECF2 No. 23), which mimic real-life use, Harper Decl. ¶ 5 (ECF No. 347); Raymond Decl. 1 ¶ 13 (ECF No. 349); Raymond Decl. 2 ¶ 4 (ECF2 No. 28), and focus on the need for adequate sample sizes. Cit. Pet. Denial Ltr. at 10 (ECF No. 341-1). But meanwhile Defendants, in particular Secretary Sebelius, argue that the data for Plan B (and Plan B One-Step) is insufficient because actual use data for every age of adolescent women who could *possibly* use EC—even ages that do not actually use it—must be provided before OTC access can be approved. *See* Defs.' Resp. to OSC at 30 (ECF2 No. 23); Memorandum from Kathleen Sebelius to Margaret A. Hamburg (Dec. 7, 2011) (ECF No. 339-1 at 2). This is a classic Catch-22. Thus, as Dr. Rosebraugh predicted years ago, "it is unclear what additional data could be provided on adolescent use that would be sufficient to lift the age restriction in the future." Tummino 31027 (ECF2 No. 31-1 at 126).

c) The FDA's Decision to Resolve the Plan B One-Step sNDA Before the Citizen Petition was Arbitrary and Capricious.

While the FDA was negotiating with Teva for years over the Plan B One-Step sNDA, it dragged its heels on complying with this Court's order that it reconsider the Citizen Petition. Despite having decided early on that new data on adolescents would be required, the FDA nevertheless held off on denying the Citizen Petition, issuing a decision only after it had denied the Plan B One-Step sNDA. Defendants argue that it was within the FDA's permissible discretion to resolve the Plan B One-Step sNDA before reaching a decision on the Citizen Petition because the data submitted with that sNDA would tell the FDA whether the additional actual use and label comprehension data it demanded had, in fact, been necessary. *See* Defs.' Opp. to Pls.' Mot. for PI/SJ at 19-20 (ECF2 No. 37). This reasoning is completely nonsensical. The FDA made clear during its negotiations with Teva regarding the then-anticipated Plan B One-Step sNDA—years before the denial of the Citizen Petition—that it considered additional adolescent data necessary. *See id.* at 21; Defs.' Opp. to Pls.' Mot. for PI/SJ, Ex. F at 2 (ECF2 No. 37-1). Given that the FDA requested this data in order to consider approving the Plan B One-Step sNDA, it is hard to see how it would ever have come to the conclusion that, in the end, the data was in fact unnecessary—and Defendants have provided no credible explanation for how this logical impossibility could have occurred.[16]

B. Plaintiffs Have Shown That Irreparable Harm Has Occurred and Will Continue to Occur in the Absence of Injunctive Relief.

As the Second Circuit has made clear, "it has always been true that irreparable injury means injury for which a monetary award cannot be adequate compensation." *Jackson Dairy Inc.*

[16] As explained above, the Plan B One-Step actual use and label comprehension studies merely confirmed the findings in the earlier studies involving the two-pill products. *Supra* at Part I at 4. Thus, if the FDA had not previously determined that such new data was necessary, it is difficult to understand how, after reviewing the results of those studies, the FDA could determine that such studies were, in fact, "essential" and "necessary" to demonstrating that EC was safe and effective for nonprescription use for adolescents. *See* Defs.' Resp. to OSC at 13-14, 17 (ECF2 No. 23). FDA, Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (Dec. 7, 2011) (ECF No. 339-1 at 4); Cit. Pet. Denial Ltr. at 3, 6, 9-10 (ECF No. 341-1).

v. H.P. Hood & Sons, *Inc.*, 596 F.2d 70, 72 (2d Cir. 1979). The essential irreparable harm in this case is that suffered by a woman who is at increased and unnecessary risk of an unwanted pregnancy that could have been avoided through the use of emergency contraception, but who was unable to obtain emergency contraception in a timely manner—or at all—because of the FDA's unnecessary and unprecedented restrictions. Because EC is more effective the sooner it is taken, any delay in obtaining it contributes to this risk. *Tummino*, 603 F. Supp. 2d at 540-41; *see also* April 27, 2012 Hr'g Tr. at 94:8-14, 110:11-14. Plaintiffs have demonstrated this harm both as to women 17 and older and as to women under 17, as explained below. In addition, several of the individual plaintiffs in this case are at risk of suffering irreparable harm if they are arrested and/or prosecuted for transferring emergency contraception to a minor in contravention of 21 U.S.C. § 353(b), which carries a punishment of up to a year in prison or a $1,000 fine, *id.* at § 333(a)(1). *Tummino*, 603 F. Supp. 2d at 540-41.

1. Plaintiffs Have Shown Irreparable Harm to Women 17 and Older, Including Individual Plaintiffs.

This Court has already recognized that the adult plaintiffs who seek to obtain emergency contraception for themselves (primarily the NWL members, including Jenny Brown) are harmed by the behind-the-counter regime that requires all women, adult or otherwise, to find an open pharmacy that stocks emergency contraception and to provide government-issued identification. *Id.*; *see also* Brown Decl. ¶¶ 4-7 (ECF No. 235-7 at 3); Order Den. Mot. to Dismiss (ECF2 No. 49). These restrictions are particularly burdensome for women who are not in a densely-populated urban area at the time that they need emergency contraception, regardless of where they usually live, Jordan Decl. ¶¶ 18-19 (ECF No. 235-7 at 3); April 27, 2012 Hr'g Tr. at 109:1-

19; Gaffin Decl. ¶¶ 4-7 (filed herewith).[17] Moreover, both women in rural areas and women in urban areas are harmed by the BTC regime because at least six states (with proposed legislation in many more) permit pharmacists and/or health professionals to refuse to dispense EC,[18] which makes access without point-of-sale restrictions all the more crucial. Even for pharmacists who dispense EC, the BTC regime produces confusion about the rules regulating access, which exacerbates the barriers, Mahoney Decl. ¶ 6 (ECF No. 235-7 at 88), Wilkinson Decl. ¶¶ 6-10 (ECF No. 350). The BTC regime increases the risk that one of the individual plaintiffs, or the women whose interests they represent, will be unable to obtain EC within the time period during which it is most effective, or effective at all, and therefore increases the risk that an individual plaintiff or women whose interests they represent will experience an unwanted pregnancy. Plaintiffs have provided specific concrete allegations of this harm. *See* Gaffin Decl. ¶¶ 4-5; Brown Decl. ¶ 4-7 (ECF No. 235-7 at 3); Mahoney Decl. ¶ 6 (ECF No. 235-7 at 88).

Defendants' primary argument to the contrary, which they claim is supported by *Whalen v. Roe*, 429 U.S. 589 (1977), is that the adult plaintiffs have no privacy interest that allows them to challenge the BTC regime. This argument, most importantly, fails to appreciate *all* the substantial barriers and harms that the BTC regime poses to all women. But even assuming Defendants were correct that the interest at issue could be limited to an informational privacy interest, the Second Circuit has specifically recognized a right to informational privacy relating to personal and medical information, a right that derives from *Whalen v. Roe* itself. *See Powell v.*

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[17] Defendants continue to rehash their objections to this Court's previous holding that Jenny Brown, and the other NWL plaintiffs, have standing based on the harms imposed on them by the BTC regime. *See* Defs.' Opp. to Pls.' Mot. for PI/SJ at 8 (ECF2 No. 37). Because this Court has settled this matter before, and reaffirmed its decision recently in open court, April 27, 2012 Hr'g Tr. at 108-09, Plaintiffs do not address Defendants' standing arguments here. To the extent that Plaintiffs address the existence of particular interests implicated by the BTC regime in this Part, it is to demonstrate that such women are in danger of irreparable harm in the absence of immediate injunctive relief. While Plaintiff Jaffe is no longer prevented from obtaining EC OTC for her own use by the age restriction, she, like any other woman or individual adult plaintiff in this lawsuit, is harmed by the behind-the-counter regime.

[18] Ariz. Rev. Stat. Ann. § 36-2154(B) (West 2012)(law is specific to EC); Ark. Code Ann. § 20-16-304(5) (West 2012) (law is specific to contraception); Ga. Comp. R. & Regs. r. 480-5-.03(n) (2011); Idaho Code § 18-611 (2012) (law is specific to EC); Miss. Code Ann. § 41-107-5 to -9 (West 2011); S.D. Codified Laws § 36-11-70 (2012) (law applies to any drug "believe[d]" to cause abortion).

Schriver, 175 F.3d 107 (2d Cir. 1999) (holding that personal privacy right established by *Whalen* and its progeny encompasses interest in the disclosure of sensitive and confidential medical information, including information relating to sexual and gender identity); *Doe v. City of New York*, 15 F.3d 264 (2d Cir. 1994); *Barry v. City of New York*, 712 F.2d 1554 (2d Cir. 1983). This right is particularly important in private medical matters that are highly sensitive and that may provoke hostility or opposition from others. *See Powell*, 175 F.3d at 110-12; *Doe*, 15 F.3d at 268. It is hard to imagine medical information more sensitive than that relating to sexual behavior, and in a society in which women's access to contraception is unfortunately highly politicized (as evidenced by this case itself), one need not look far to find evidence that publicly announcing a need for EC in front of strangers at a pharmacy might provoke hostility not only from other customers but potentially even from the pharmacist in question.[19] Thus, while the invasion of informational privacy is not the only form of harm at issue in this case, standing alone, it nevertheless is both firmly rooted in this Circuit's case law and imperiled by the FDA's arbitrary and capricious actions.

2. Plaintiffs Have Demonstrated Irreparable Harm to Women Under 17, Including Individual Plaintiffs.

Women under the age of 17 are at particular risk of unwanted pregnancy as a result of an inability to obtain EC in a timely manner. These women must first find a doctor and obtain a prescription in very short order, which can be difficult for any woman, and particularly for an adolescent who may not have her own transportation or control of her schedule. Gaffin Decl. ¶¶ 5-6; Kelley Decl. ¶¶ 6-8 (filed herewith)**.** Those young women then must navigate the behind-

[19] *See, e.g.*, In re Noesen, Case No. 01 PHM 080 (April 13th, 2005), *available at* https://online.drl.wi.gov/decisions/2005/ls0310091phm-00068882.pdf (pharmacist refused to refill student's birth control and refused to transfer the prescription to another pharmacy because of his personal disapproval of the use of contraceptives); Chris Blank, *Missouri House Endorses Contraception, Abortion Refusal Legislation*, The Associated Press, May 16, 2012, http://www.columbiamissourian.com/stories/2012/05/16/missouri-house-endorses-contraception-abortion-refusal-legislation/ (Missouri legislature approved law that would allow pharmacies to refuse to provide contraceptives because of their religious or ethical beliefs).

the-counter regime and the point-of-sale restrictions it entails, which are particularly burdensome since this group is less likely than adults to have government identification. The irreparable harm of an unwanted pregnancy that could have been prevented with timely access to EC is particularly significant for younger women, who "are more likely to face a range of challenges and adverse conditions when it comes to the health and economic security of themselves and their children."[20]

Defendants can hardly argue that an unwanted pregnancy that could have been prevented does not constitute irreparable harm for an adolescent. Instead, they continue to assert that Plaintiffs do not have standing to challenge the prescription-only requirement for women under age 17. Defs.' Opp. to Pls.' Mot. for PI/SJ at 2 (ECF2 No. 37). But this Court has rejected this argument multiple times. *Tummino*, 603 F. Supp. 2d at 540-41; April 27, 2012 Hr'g Tr. at 108-09, 101:18-25.[21] Moreover, Plaintiffs have moved to add two additional plaintiffs to this case who have unquestionable standing to challenge the age restrictions on EC. One, Anaya Kelly, is a fourteen-year-old girl. Kelley Decl. ¶¶ 1-3. Ms. Kelly desires to be able to obtain EC without a prescription as soon as possible after any future sexual activity, and believes the current age and other point-of-sale restrictions would prevent her from doing so. *Id.* ¶¶ 4-8. The other additional plaintiff, Tracy Gaffin, is the mother of a twelve-year-old girl and a fourteen-year-old-girl, and challenges the age restriction on behalf of her daughters. Gaffin Decl. ¶¶ 2-3. Ms. Gaffin is

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[20] *See, e.g.,* HHS, *Reduce Teen and Unintended Pregnancy*, http://www.hhs.gov/secretary/about/reduce.html (last visited May 22, 2012).

[21] While Angela Jaffe is no longer in a position to suffer imminent harm from the age restriction on EC (although she still suffers irreparable harm from the behind-the-counter regime just like any woman 17 and older, *see supra*), the other plaintiffs in this case (the NWL and ARHP plaintiffs) have third-party standing to represent the interests of minor women generally. *See Eisenstadt v. Baird*, 405 U.S. 438, 445 (1972) (holding that plaintiff who had distributed contraceptives illegally had standing to challenge law not only on his own behalf but on behalf of unmarried persons barred by the law from obtaining contraceptives because "the relationship between Baird and those whose rights he seeks to assert is not simply that between a distributor and potential distributees, but that between an advocate of the rights of persons to obtain contraceptives and those desirous of doing so."); Tummino Decl. ¶¶ 2-6 (ECF No. 235-7 at 93); Mahoney Decl. ¶¶ 2-5, 7 (ECF No. 235-7 at 88),; Brown Decl. ¶¶ 2-3, 7-9 (ECF No. 235-7 at 3). At the very least, they have standing to represent the minor women to whom NWL members would like to, or are likely to, distribute EC, Tummino Decl. ¶¶ 3-4, 6 (ECF No. 235-7 at 93); Mahoney Decl. ¶¶ 3, 5, 7 (ECF No. 235-7 at 88); Brown Decl. ¶¶ 7-8 (ECF No. 235-7 at 3), and the minor women who are patients of AHRP members, Wilkinson Decl ¶¶ 1-2 (ECF No. 350). ARHP also has associational standing to represent its members and the rights of their patients, either as an organization, or because it has associational standing to represent Dr. Tracy Wilkinson, who has third-party standing to represent the rights of her patients. Wilkinson Decl ¶¶ 1-4 (ECF No. 350).

concerned that her daughters would not be able to access EC in a timely manner because of the age and point-of-sale restrictions. Gaffin Decl. ¶¶ 3, 5. These plaintiffs have standing to challenge the age restriction for the same reasons that this Court found the original adolescent plaintiff and her mother did in its 2009 opinion. *Tummino*. 603 F. Supp. 2d at 539-541.

Thus, unless this Court grants injunctive relief, minor women generally, and the individual minor women represented in this lawsuit, will be subject to the irreparable harm of an increased risk of unwanted pregnancy that could have been prevented with timely access to EC.

3. Plaintiffs Who Risk Arrest and Prosecution for Transferring EC to A Woman Under 17 Are Irreparably Harmed.

As this Court has already recognized, adult women who wish to obtain EC and transfer it to women under the age of 17 are at risk of arrest and prosecution for doing so. *Tummino*, 603 F. Supp. 2d at 540-41. As a district court in the Eastern District of New York has recently recognized, the risk of arrest and prosecution can constitute irreparable harm that satisfies the standards for injunctive relief. *See Jefferson v. Rose*, 2012 WL 1398743, at *4 (E.D.N.Y. April 23, 2012). At least two individual plaintiffs in this lawsuit, Erin Mahoney and Tracy Gaffin, have declared that they desire to transfer EC to women under the age of 17, but that they fear arrest and prosecution if they do so. Mahoney Decl. ¶¶ 3-5, 7-8 (ECF No. 235-7 at 88); Gaffin Decl. ¶¶ 1-2, 8. These plaintiffs must therefore act against their conscience and their belief that access to EC would improve women's health (and for Gaffin, her belief that providing her daughters with EC would be the responsible thing to do as a parent) in order to avoid arrest and prosecution for violating arbitrary and capricious regulations restricting access to EC.

C. Granting Plaintiffs' Requested Preliminary Injunction Would Benefit the Public Interest.

A preliminary injunction would clearly benefit the public interest. Nearly half of pregnancies in the United States are unintended, and EC is a crucial part of reproductive health care for women of all ages. Jordan Decl. ¶ 14 (ECF N0. 235-7 at 76); see also Grimes Decl. ¶¶ 3, 9. Women have been denied full OTC access to this safe, effective contraceptive for over ten years due to the FDA's arbitrary and capricious conduct and its willingness to bow to political pressure instead of protecting public health. Women of all ages have waited long enough and should not have to wait any longer—every day that EC remains subject to the age and point-of-sale restrictions is a day that women in this country, including individual plaintiffs, are at increased risk of becoming pregnant when they do not want to be.

D. The Requested Preliminary Injunction Is Both Within This Court's Power and The Proper Remedy In This Case.

Plaintiffs seek an order directing the agency to permit EC to be made available OTC without restriction immediately. Defendants continue to argue, as they have throughout this litigation, that this Court is powerless to grant Plaintiffs the relief that they seek.[22] They make this argument to: (1) in the short term, delay or prevent this Court from ruling, in order to buy more time to seek a compromise with Teva might appease Teva and the FDA, but would be harmful to all women who are not included in whatever compromise they reach, and (2) in the

[22] Defendants have argued that this Court should not issue preliminary relief because to do so would short-circuit the FDA's negotiations with Teva. Defs.' Resp. to OSC at 42-44 (ECF2 No. 23). That argument discounts who the Plaintiffs in this suit are—consumers in need of EC and not the drug manufacturer—and the full relief they have been seeking for years: full over the counter access without any age of point-of-sale restrictions. During the April 27, 2012 oral argument, counsel for Teva acknowledged that it was currently in talks with the FDA in an attempt to obtain a solution "more palatable" to the FDA than unrestricted OTC status for Plan B One-Step, April 27, 2012 Hr'g Tr. at 22-23, which likely means a lowered age cut off with the burdensome BTC regime kept in place. This solution, which the FDA seems in a hurry to reach so as to possibly thwart an order by this Court, will continue to deny Plaintiffs the full relief they seek, which is clearly warranted by the scientific evidence, and which the FDA continues to arbitrarily deny. (This desire for a fast "solution" is evidenced by the fact that Defendants have assured this Court that the FDA would consider any new Plan B One-Step sNDA "in due course," Defs' Resp. to OSC at 36 fn.7 (ECF2 No. 23), and in doing so cited to the regulations for manufacturing supplements, which call for review in four to six months, *id.*, even though it is impossible to see how a revised sNDA for Plan B could possibly be a manufacturing supplement, which is used for changes to the manufacturing process, not the labeling or dispensing instructions. A labeling supplement, which is what a Plan B One-Step sNDA would undoubtedly actually be, has a review goal of 10 months. Def.'s. Mem. in Opp'n to Contempt, Ex. G.(ECF No. 316-7)).

long term, attempt to convince this Court to simply defer to the FDA's arbitrary and capricious actions. In pursuing these goals, Defendants mischaracterize the relief Plaintiffs seek. First, Defendants inaccurately contend that Plaintiffs seek reversal of the Plan B One-Step sNDA. Plaintiffs have made clear that this is incorrect. *See supra* Part II(A)(3). Second, Defendants contend that Plaintiffs seek an order directing the FDA to grant the Citizen Petition. Def.'s Opp. to Contempt at 12-16 (ECF No. 315).[23] But Plaintiffs do not seek such relief. (Plaintiffs believe that Defendants are attempting to characterize Plaintiffs' sought relief this way so that if this Court grants Plaintiffs any relief, it will do so by ordering the FDA to grant the Citizen Petition, thus allowing the FDA to begin an unnecessary (*see supra* n.23) and indefinite rule-making process instead of granting OTC access to EC immediately). The form of remedy that Plaintiffs actually seek is explained in further detail below.

1. Plaintiffs' Requested Remedy Is Permissible and Feasible.

Defendants incorrectly claim that an order directing the FDA to immediately permit EC to become available OTC without age or point-of-sale restrictions is an improper remedy. *See* Defs.' Opp. to Pls.' Mot. for PI/SJ at 12-14 (ECF2 No. 37). In fact there are multiple uncomplicated ways in which the FDA could comply with such an order, none of which would require this Court to order the FDA to take any action on the Plan B One-Step sNDA, nor to do anything it does not otherwise have authority to do. Indeed, each is something that the agency

[23] Even if this Court were to order the FDA to grant the Citizen Petition, Defendants are simply wrong that such an order would have to result in rule-making. Plaintiffs believe that the legislative history of the Citizen Petition process demonstrates that citizens may, via a Citizen Petition, initiate the OTC switch of a drug without rule-making by the FDA. Further, the FDA's argument that it is *required* to engage in rule-making is belied by the text of the statute, which states that the Commissioner "may" by regulation move a drug from prescription to OTC status. 21 U.S.C. § 353(b)(3). The statute does not say "must" or "shall"—thus the use of a rulemaking to switch a drug from prescription to OTC status is discretionary, not mandatory. *Id.* Moreover, there is no need for the FDA to engage in rule-making because the applicable regulations allow the Commissioner to resolve the Citizen Petition by taking any action that is warranted. 21 C.F.R § 10.30(e)(3) ("The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants."); Pendergast Decl ¶ 28 (ECF No. 348). Indeed, the Commissioner is specifically authorized to exempt any new FDA regulation from the regulations governing rule-making if she "determines for good cause that they are impracticable, unnecessary, or contrary to the public interest." 21 C.F.R. § 10.40(e)(1).

could—and should—have done on its own authority at any time over the past decade based on the scientific evidence of EC's safety and effectiveness for self-medication.

As the history of this litigation shows, to make a drug that was previously prescription-only available OTC for a given population, all the FDA needs to do is invite drug companies to submit labeling supplements to the FDA. This is exactly what the FDA did in 2009 to comply with this Court's order that it make EC available without a prescription to women 17 and older. Letter from Andre Leonard-Segal to Duramed Pharmaceuticals, Inc. at 2 (Dec. 17, 2010) (ECF2 No. 23-3); *see also* Pendergast Decl. ¶ 7 (ECF No. 348) (explaining that, consistent with FDA precedent, the FDA published a notice in the Federal Register in 1997 inviting drug manufacturers to submit applications to make oral contraception products labeled for post-coital use). *See also* Prescription Drug Products; Doxycycline and Penicillin G Procaine Administration for Inhalational Anthrax (Post-Exposure), 66 Fed. Reg. 55679 (Nov. 2, 2001) (inviting drug manufacturers to submit labeling changes for new dosage instructions for use for doxycycline, an antibacterial drug). The FDA has provided no explanation for why it could not proceed in exactly the same way as to EC. Indeed, the FDA could switch approved EC products from prescription to OTC status without inviting such requests. Pendergast Decl. ¶¶ 16, 23, 26-27 (ECF No. 348). The FDA is authorized to make such a switch when it finds that prescription requirements are not necessary for the protection of public health. 21 C.F.R § 310.200(b) ("[a] proposal to exempt a drug from [] prescription-dispensing requirements . . . may be initiated by the Commissioner."); *see also* Pendergast Decl. ¶ 23 (ECF No. 348). Moreover ,the FDA could also exercise its enforcement discretion and announce that it would not take any enforcement action against EC sold OTC, whether indefinitely or while the FDA waits for sNDAs containing OTC labeling to be submitted. Pendergast Decl. ¶ 27 (ECF No. 348).

Defendants argue that this Court should not issue such an order because, as a practical matter, it would be difficult or impossible to reverse the effects of a preliminary injunction if Defendants were to prevail on appeal. But Defendants fail to provide a single reason as to why this is so. Defs.' Opp. to Pls.' Mot. for PI/SJ at 5 (ECF2 No. 37). In fact, returning to the status quo could be easily accomplished, should it prove necessary. The FDA already has a frequently-utilized drug recall framework in place. *See, e.g.*, FDA, U.S. Food and Drug Administration: Drug Recalls, http://www.fda.gov/drugs/drugsafety/DrugRecalls/default.htm (last visited May 22, 2012). If it were necessary to return to the current status quo, the FDA would merely need to submit a recall alert into the FDA electronic data system and thereafter, a retailer would simply remove EC from public access—requiring minimal effort. Given that the FDA utilizes this procedure several times a month on average, *id.*, Defendants' assertions that this would somehow be a herculean, if not impossible, task, are clearly without merit. In fact, this process would be less burdensome than most drug recalls because there would be no immediate risk to public health and safety requiring additional ameliorative measures. *Cf. Tummino*, 603 F. Supp. 2d at 522 (levonorgestrel "does not have any known serious or long-term side effects").

2. Remand Would Serve No Purpose Here.

Given the history of this case, and the FDA's repeated failure to engage in good-faith consideration of OTC switch requests for EC even after remand, an injunction, rather than another remand, is the only appropriate remedy. It has been over three years since this Court found that the FDA acted arbitrarily and capriciously. *See Tummino*, 603 F. Supp. 2d at 547-48. As this Court recognized in its order, "[w]here a court has found that an agency decision is not supported by the record, but the record has been fully developed, remand would fail to serve a useful purpose." *Id.* at 549 (quoting *Sierra Club v. EPA*, 346 F.3d 955, 963 (9th Cir. 2003)).

Here, the record has been fully developed. The scientific and medical evidence in question supports making EC available OTC to all ages. Thus, contrary to Defendants' arguments, *see* April 27, 2012 Hr'g Tr. at 58, in granting an injunction this Court would not be making a scientific determination itself, but rather would merely be implementing the scientific determinations that the FDA has consistently ignored.

This case is strikingly similar to *Greyhound Corp.,* 668 F.2d at 1354. In that case, Greyhound had initially challenged the Interstate Commerce Commission's ("ICC") continued regulation of it as a non-carrier holding company (which meant the ICC restricted its ability to make certain investments) even after it had diversified its holdings and should no longer have qualified for such regulation. *Id.* In 1977, the D.C. Circuit found that the ICC had not provided adequate explanation for why it had changed the rules concerning when a company would be regulated in this manner and why it had treated Greyhound's petition differently than similar petitions, and remanded to the agency. *See Greyhound Corp. v. Interstate Comm. Comm'n*, 551 F.2d 414, 417 (D.C. Cir. 1977). In two orders in 1978 and 1979 the ICC affirmed its previous conclusion, and Greyhound brought suit again. The D.C. Circuit ordered that Greyhound be released from the securities trading restrictions, holding that the ICC's actions were arbitrary and capricious because it had failed to provide any credible explanation for its behavior. *See Greyhound Corp.*, 668 F.2d at 1360.

Part of the reason for this Court's 2009 order was the FDA's failure to credibly explain its multiple departures from agency norms. *See Tummino*, 603 F. Supp. 2d at 548. This Court remanded with the hopes that a change in the FDA's leadership would result in a fair assessment of the evidence. *Id.* at 549. But those hopes did not materialize. The agency has again failed to provide a fair review. And now, three years later, the FDA has still provided no explanation for

its departure from agency norms. The record was fully developed even before remand, and at this point it has been supplemented both with more data and more evidence of arbitrary and capricious FDA action. Thus, it is clear that remand would serve no useful purpose. *Id.*; *see* April 27, 2012 Hr'g Tr. at 45 (wondering for what purpose this Court should remand since FDA's response to prior remand was to make the same decision again and argue it was justified based on the prior record found to be inadequate).

To remand again would unnecessarily "convert judicial review of agency action into a ping-pong game," *NRLB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969), that would serve only to delay justice even longer. As in *Greyhound Corp.*, the agency "has had ample time and opportunity to provide a reasoned explanation" of its treatment of EC, and there is "no useful purpose to be served by allowing [it] another shot at the target." *Greyhound Corp.*, 668 F.2d at 1364. *See also Hamm v. Sec'y of HHS*, 704 F. Supp. 2d 357 (W.D.N.Y. 1989) (reversal without remand appropriate because of Secretary's consistent failure to obey the law with regard to the challenged rule). In this case, this Court already found that the FDA's prior decision was arbitrary and capricious—and on remand, the FDA made the exact same decision without providing the necessary explanation. It is clear that when it comes to the FDA and EC, politics are *always* at play at the expense of scientific deliberation.

In sum, a preliminary injunction is warranted, and it is within this Court's power to grant Plaintiffs their requested relief. Even if this Court believes it must wait for the administrative record in order to rule on Plaintiffs' Motion for Summary Judgment—which Plaintiffs do not believe is necessary, *see infra* Part III—this Court can and should grant Plaintiffs preliminary injunctive relief at this stage of the proceedings.

III. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON THEIR CLAIM THAT THE FDA'S ACTIONS ON REMAND WERE ARBITRARY AND CAPRICIOUS.

Plaintiffs are entitled to summary judgment under Rule 56(c) "'if the pleadings, depositions, answer to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that [Plaintiffs are] entitled to judgment as a matter of law.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). The party opposing summary judgment on the ground that there are disputed facts must present significantly probative evidence in opposition to a motion for summary judgment. *Scotto v. Almenas*, 143 F.3d 105, 114 (2d Cir. 1998) (the party opposing summary judgment must produce specific facts indicating that a genuine factual issue exists). Mere assertions or allegations will not suffice. All factual contentions must be made or opposed by the methods set out in Rule 56(c). *See* Fed. R. Civ. P. 56(c)(1), (4) ("A party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . citing to particular parts of the materials in the record" or submitting affidavits or declarations based on personal knowledge).

There are no genuine issues of material fact present to preclude summary judgment in Plaintiffs' favor. The undisputed evidence shows that the FDA's "plan of action" upon remand, and execution thereof, were arbitrary and capricious. Indeed, in their memorandum opposing Plaintiffs' motion for summary judgment, Defendants barely address Plaintiffs' evidence but instead, erroneously mischaracterize Plaintiffs' arguments as a nonjusticiable, unreasonable

delay claim. Defs.' Opp. to Pls.' Mot. for PI/SJ at 17 (ECF2 No. 37).[24]

Defendants attempt to create the illusion of factual issues and spend a great deal of time disputing already established facts, such as that the FDA treated the Plan B sNDAs and Citizen Petition as intertwined, *see Tummino,* 603 F. Supp. 2d at 537, 543, and that "as early as April 2002, the FDA informed the Plan B sponsor that results from trials in the adult population could be extrapolated," *see id.* at 526-27; see also Defs.' Resp. to Pls.' R. 56.1 Statement of Material Facts Not in Dispute at 4-32 (ECF2 No. 38). In other instances, Defendants fabricate disputes where none actually exist, by rephrasing Plaintiffs' allegations or challenging immaterial word choices made by Plaintiffs or this Court. *Compare Tummino*, 603 F. Supp. 2*d* at 532 (The FDA denied the first sNDA, informing the sponsor that "it needed to provide more information on safe use by women under 16, or more information in support of a dual marketing plan that would sell Plan B as a prescription-only product to women under 16") *with* Defs.' Resp. to Pls.' R. 56.1 Statement of Material Facts Not in Dispute at 15 (ECF2 No. 38) ("The quotation…represents the Court's paraphrasing of the letter's content, and not a statement by the FDA."); Harper Decl. ¶ 5 (ECF No. 347) ("The purpose of an actual use study is to simulate the OTC use of a product and predict if a drug will be used correctly, safely, and effectively in the OTC setting.") *with* Defs.' Resp. to Pls.' R. 56.1 Statement of Material Facts Not in Dispute at 8 (ECF2 No. 38) ("[a]ctual use studies are trials designed to assess how consumer actually use the product in an OTC setting. These trials are usually open-label and are designed specifically to assess consumer use, but they may also provide information about safety.") [25]

[24] Defendants refer to Plaintiffs' claim as an "omnibus action" challenging three separate events. Defs.' Opp. to Pls.' Mot. for PI/SJ at 15 (ECF2 No. 37). But Plaintiffs' cause of action under the APA deals with only one thing—the FDA's reconsideration of the Citizen Petition on remand, culminating in its denial. How the agency acted, in particular its treatment of the Plan B One-Step sNDA, which the FDA inextricably intertwined to the review of the Citizen Petition on remand (Def.'s. Mem. in Opp'n to Contempt at 20-21 (ECF No. 315); Cit. Pet. Denial Ltr. at 2 (ECF 341-1); Dec. 13 Tr. at 30-31) is evidence of the FDA's arbitrary and capricious handling of the Citizen Petition. *See Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 891 (1990), relied upon by Defendants (Defs.' Opp. to Pls.' Mot. for PI/SJ at 15 (ECF2 No. 37)) is inapposite. In *Lujan*, the plaintiff challenged an entire agency program and regulation under the APA, not a concrete action. *Id.* Here, there is no question that denial of the Citizen Petition is both a concrete agency action and that it is properly before this Court. *See* 5 U.S.C. § 706(2)(A) (granting a district court jurisdiction to hold unlawful and set aside agency findings that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

Although Defendants have indicated that they plan to file a motion for summary judgment of their own, April 27, 2012 Hr'g Tr. at 144:8-12**,** they were required to present significantly probative evidence in opposition Plaintiffs' motion for summary judgment in order to defeat it on the ground that there are disputed facts. *See Scotto*, 143 F.3d at 114. They have failed to do so. Accordingly, Plaintiffs are entitled to summary judgment on their claim that the FDA's actions were arbitrary and capricious, and are therefore entitled to permanent injunctive relief ordering the FDA to allow all forms of levonorgestrel-based EC to be made available to all women OTC without point-of-sale restrictions.

IV. CONCLUSION

The first time around, this Court found that the FDA's decision to block access to this safe, effective, and life-altering medication for younger women was arbitrary and capricious. Rather than follow this Court's ruling and its own responsibility to public health on remand, the FDA chose instead to adhere ever more firmly to its previous arbitrary and capricious decision, and deny Plaintiffs a fair and honest consideration of the Citizen Petition. Plaintiffs respectfully request that this Court immediately grant a preliminary injunction ordering the FDA to make EC available OTC to women of all ages without point-of-sale restrictions, and further grant summary judgment in their favor.

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[25] Defendants also appear to deliberately misread a number of factual statements in order to manufacture issues that this Court need not address. For example, the FDA disputes the fact that Dr. Galson's decision was novel and did not follow FDA's traditional practices by stating that "a determination that an OTC switch is not appropriate due to inadequate data is not novel." Def.'s Resp. to Pls.' R. 56.1 Statement of Material Facts Not in Dispute (ECF2 No. 38); *but see* Pls.' Mot. for PI/SJ at 9 (ECF2 No. 2) ("The GAO Report found several irregularities, including novel justifications about adolescents' cognitive development, which this Court found significant in holding the FDA's actions with respect to Plan B were arbitrary and capricious."). Plaintiffs do not intend to suggest that inadequacy of data itself is novel, but rather that, as the GAO and this Court already found, when the FDA considered the Citizen Petition, aspects of the FDA's review process were "departure[s] from its normal procedure for evaluating OTC switch applications'" *Tummino*, 603 F. Supp. 2d at 547, and the consideration of cognitive development was unprecedented, *see* GAO Report at 5-6 (ECF No. 68).

Dated: May 23, 2012

Respectfully submitted,
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